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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,290	06/20/2003	Sean D. Monahan	Mirus.013.03.1	8545
25032	7590	04/17/2006	EXAMINER	
MIRUS CORPORATION 505 SOUTH ROSA RD MADISON, WI 53719			WOITACH, JOSEPH T	
			ART UNIT	PAPER NUMBER
			1632	
DATE MAILED: 04/17/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/600,290

Applicant(s)

MONAHAN ET AL.

Examiner

Joseph T. Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-31 is/are pending in the application.
- 4a) Of the above claim(s) 14,17,21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15, 16, 18-20, 23-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a Divisional from non-provisional application US Serial No. 09- 447966, issued, which is a Continuation-in-part from nonprovisional application 09/391,260, filed September 7, 1999 which is a Divisional from nonprovisional application 09/975,573, issued as U.S. Patent 6,265,387, which is a Continuation from 08/571,536, filed December 13, 1995, abandoned.

Claims 1-12 have been canceled. Claims 13-31 are pending.

Examiner's comment

As indicated in Applicants' response, the restriction requirement for 10/600,098 and 10600,290 were inadvertently switched, and entered and mailed under the wrong application number. The restriction requirement (present in '098) is set forth below for clarity and completeness of the record.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 19, 20, 22, 14-18, 23-28, 30 and 31, drawn to a process for delivering an oligonucleotide that is not expressed (such as an anti-sense oligo), classified in class 514, subclass 44.
- II. Claims 21, 14-18, 23-28, 30 and 31, drawn to a process for delivering an gene sequence to be expressed, classified in class 514, subclass 44.

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Claims 13 and 29 link(s) inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 13 and 29. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions use different starting materials/products and if successfully practiced would result in different outcomes

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter,

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and the search of one group would not be the same nor commensurate in scope with that required of the other group, restriction for examination purposes as indicated is proper.

In addition, this application contains claims directed to the following patentably distinct species of the claimed invention: specifically, the claims encompass the use of a sub-genus of nucleic acids comprising: 1) dsRNA, 2) ssRNA, 3) dsDNA, and 4) ssDNA. While literal support would allow for the use of any of these in either the two claimed methods, certain species of these sub-genus of sequences may only be consistent with only one of the elected groups.

If any of group I or II is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 14-18, 23-28, 30 and 31 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicants' Election

Applicant's election of Group I and the species of dsRNA in the reply filed on February 7, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13-31 are pending. Claims 14, 17, 21, 22, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 7, 2006. Claims 13, 15, 16, 18-20, 23-31, drawn to a process for delivering an dsRNA that is not expressed are currently under consideration.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

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The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/391,260, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Upon a search of the present specification as well as the priority documents, the literal support for the range of "10 to 50" or "18 to 25" bases can not be found, nor is there general guidance for RNA molecules of any size. Double stranded RNA appears finds literal support in paragraph 25, however this appears to be applicable to only the specific species of RNA discussed in the paragraph. The specification teaches "these forms of DNA and RNA may be single, double, triple or quadruple stranded" (*emphasis added*) referring to tRNA, snRNA, rRNA, antisense RNA and ribozymes discussed earlier in the paragraph. Further, given this guidance, and the lack for any specific function associated with the RNA except ones that would inherently be associated with tRNA, snRNA, rRNA, anti-sense RNA and ribozymes, there is no support for decreasing "expression of a gene" (claim 24), in particular if they were present as a double stranded RNA.

Accordingly, claims simply encompassing/reciting the delivery of double stranded RNA have the priority date of November 23, 1999, the filing date of 09/447,966,

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and claims encompassing embodiments first presented in this application have the priority date of June 20, 2003.

Claim Objections

Claims 13, 15, 16, 23-31 are objected to because of the following informalities: the elected invention is drawn to a process for delivering an dsRNA that is not expressed, however the claims as pending are broader.

Appropriate correction is required.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). In the instant case, the claims have been amended to recite ranges and affects for practicing the method with dsRNA, however support for these embodiments is not recited or generally defined in the instant specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 15, 16, 18-20, 23-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

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to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". As discussed above in the priority section, the elected invention is directed to the delivery of double stranded RNA, however while there is literal support for RNA that is double stranded, it is the context of tRNA, snRNA, rRNA, antisense RNA and ribozymes. Further, there is no support for the size ranges contemplated or for the use to reduce the "expression of a gene" in particular with double stranded RNA.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 13, 15, 16, 18-20, 23-31 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described. In this case, without the specific guidance in the present specification for practicing the methods as claimed, one of skill in the art would be required to practice undue experimentation to practice the claims. Examiner does not contest that dsRNA is known in the art, and an area of active research. However, given the guidance in the specification for the use of only the species of double stranded forms of RNA consisting of tRNA, snRNA, rRNA, anti-sense RNA and ribozymes the skilled artisan would not be directed to what is or was known in the art. Moreover, double stranded forms of anti-sense RNA and ribozymes would be inconsistent with their activity described in the art.

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MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a

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nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13, 15, 16, 18-20, 23-31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,627,616 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because in this case '616 provides the same method of delivery of any polynucleotide, and given this any particular type of polynucleotide would be obvious in light of the teachings of the instant specification.

It is noted that the instant application has been designated as a divisional, however upon review of the history of '616 a restriction requirement was not done. While the original claims of the instant application were cancelled and new claims entered, as discussed above the subject matter regarding the general method of delivery covered by the new claims is co-extensive and obvious for the delivery of dsRNA or any polynucleotide.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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